

### **Remarks**

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

### ***Status of All of the Claims***

Below is the status of the claims in this application.

1. Claim(s) pending: 1-14, 16-32, 34-37, 47-49, and 51-60.
2. Claim(s) canceled: 15, 33, 38-46, and 50.
3. Claim(s) added: 55-60.
4. Claims withdrawn from consideration but not canceled: 18, 25, 26, 28-31, and 49.

### ***Claim Support***

It is believed that the new and amended claims are supported by the application as originally filed. For example, support for claims 1, 32, 47, and 55-60 can be at least found at pages 9, 10, and 14-16 of the specification and FIGS. 1-3 of the drawings. The amendments to claims 10, 16-19, and 34 are merely formalistic in nature. Further, it is submitted that new claims 55-60 read on the elected Species I (FIGS. 1-3).

### ***Interview***

The applicant's representative first wishes to thank Examiners Lloyd and Hindenburg for the telephonic interview conducted on October 31, 2007. During the interview, proposed claim amendments were presented and discussed in view of the references cited in the Office Action. In particular, Examiner Lloyd helped to clarify the 35 U.S.C. §112, second paragraph rejection of item 8 of the Office Action. Based on the discussion at the interview, it is believed that the above amendments to the claims have addressed the 35 U.S.C. §112 issue. U.S. Patent No. 6,143,164 to Heller and U.S. Patent Application Publication No. 2003/0028087 A1 to Yuzhakov et al. were also discussed in view of the proposed claim amendments. Although no definitive agreement was reached as to the allowability of the proposed claims, as will be explained below, the claims have been amended in such a manner so as to address the Examiners' concerns raised at the interview. The substantive comments from the interview have been incorporated into the remarks below.

### ***Information Disclosure Statement***

As a housekeeping matter, it should be noted that an Information Disclosure Statement (IDS) has been submitted with this response. The Applicants kindly request that the Examiner return an initialed copy of the IDS form with the next communication from the Patent Office.

### ***Specification***

The specification has been amended to correct the informalities cited in item 4 of the Office Action. No new matter has been added.

### ***Claim Informalities***

Claims 1, 10, and 32 have been amended to correct the informalities cited in items 6 and 8 of the Office Action.

### **Technological Background**

Most home (or medical) blood testing kits have separate systems for forming an incision in the skin and collecting the blood (or other body fluid) from the incision. For example, diabetics test kits typically have a pen-type lancet injector for forming the incision that is separate from the test strips and meter used to collect and analyze the blood. Integrated devices have been proposed that are able to perform, or integrate, both of these functions together. Although numerous integrated devices have been proposed, as to date none of them have been commercially successful due to several factors.

One factor is that the integrated devices have not been able to achieve commercially successful test success rates. By their very nature of having all the testing functions incorporated into a single device, any failure in the fluid collection and testing process can lead to testing failure. Without achieving testing success rates comparable to today's non-integrated technology, consumers are unlikely to adopt the use of integrated devices. Complicated integrated systems have been proposed to improve the chance of successful testing. For example, integrated systems with vacuum expression devices to increase bleeding from the incision have been tried, but in the real world, these vacuum type integrated devices have

commercially failed due to the size, the testing success rate, and cost of the device, among other reasons.

One type or category of integrated device, which is sometimes referred to as “integrated disposable” or “lancet integrated test strips”, typically incorporates a lancet or other means for forming an incision with a test strip or other fluid testing means. With integrated disposables, the less expensive parts that are contaminated with blood during testing, such as the lancet and test strip, are designed to be expendable such that the integrated disposable is disposed of and replaced with a new one after use (hence, the term “integrated disposable”) while the more expensive components of the meter such as the electronics and firing mechanism are re-used for subsequent testing. Although integrated disposables typically provide a compact and inexpensive design, there are still a number of significant obstacles that need to be overcome before integrated disposables become commercially viable.

One obstacle concerns the co-related issues of manufacturability and expense. Generally speaking, the integrated disposable needs to be easily manufactured so that it can be inexpensive to produce, which is more of a concern in view of the fact that the integrated disposable is discarded after each use. Two general designs have been proposed for integrated disposables, one in which the lancet (or other incision forming means) is able to move relative to the rest of the disposable and another one in which the lancet is fixed.

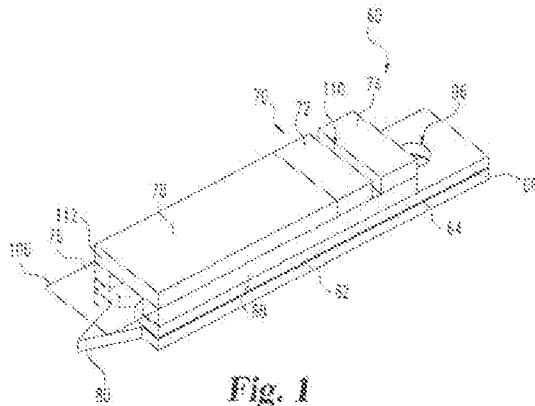
When the lancet is able to move relative to the rest of the disposable, the lancet is typically retracted out of the way so that the lancet does not interfere with fluid collection or injure the patient. However, integrated disposables with moveable lancets experience several drawbacks. For instance, the moveable lancet makes assembly of the integrated disposable more difficult, thereby making the integrated disposable more expensive to produce. Loading and firing of the integrated disposable is more problematic. The moveable lancet is also prone to damage or failure, and with the complex nature of the firing mechanism, penetration depth of the lancet can be variable to the extent that insufficient fluid volumes are bled from the incision.

Integrated disposables with fixed lancets (or other incision forming means) tend to be less expensive to produce and usually are easier to fire. However, the fixed lancet designs experience problems of their own in other areas, such as fluid collection. Fluid collection in integrated devices typically occurs in one of two ways, either the fluid is collected from below the skin’s surface like a mosquito or on the skin’s surface like a vampire bat. Integrated disposables with

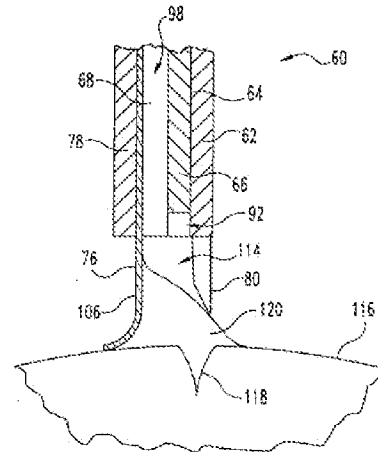
fixed needles (or other incision forming means) have been proposed that collect fluid below the skin in a fashion similar to a mosquito or syringe. As should be appreciated, collecting fluid in such a manner can be quite painful because the needle remains below the skin as fluid is collected. Further, although mosquitoes can collect fluid beneath the skin quite easily, the problem of collecting fluid beneath the skin has been problematic due to several factors, such as clotting and debris clogging the needle.

With the fixed lancet type integrated disposables, fluid collection above the skin has been considered difficult or even practically impossible. The position of the integrated disposable relative to the skin controls whether or not successful fluid collection occurs. Unlike integrated disposables that have moveable lancets that are able to retract out of the way during fluid collection, fixed lancet integrated disposables do not have such a luxury. With fixed lancet integrated disposables, the lancet can be positioned too close the skin such that the lancet forms additional painful incisions in the skin, which is clearly undesirable. In addition, the fixed lancet can block or constrict bleeding from the incision when positioned too close. On the other hand, the integrated disposable can be positioned too far away from the skin such that it is unable to collect the fluid sample. Variations in skin elasticity and control tolerances of the firing/positioning mechanism as well as other variables have made precise and consistent positioning of fixed lancet integrated disposables relative to the skin during fluid collection nearly impossible. Consequently, fixed lancet designs have been considered not a commercially practical solution.

The inventors for the present application have invented a unique and inventive integrated disposable that solves these problems by using a flexible hydrophilic film or sheet to draw fluid into the capillary channel. To aid in the discussion, FIGS. 1 and 3 from the present application have been reproduced below.



**Fig. 1**



**Fig. 3**

As can be seen, the integrated device (60) includes a fixed lancet (62) with a tip (80) that extends from the capillary channel opening (100). Extending generally parallel to the lancet (62), the sampling end portion (106) of the fluid collection sheet (76) extends past the opening (100) of the capillary channel (98) so as to promote drawing of the bodily fluid sample into the channel (98) from the surface of the skin (116), as is depicted in FIG. 3. With the channel opening recessed from the lancet tip, the issues normally associated with below the skin (mosquito) fluid collection techniques, such as capillary channel blockages due to skin or other debris, are avoided. Further, this configuration allows the capillary channel opening to be larger than would be possible with the mosquito collection technique due to pain considerations, which in turn allows greater amounts of fluid to be collected in shorter periods of time. Due its flexible nature, sampling end portion (106) of the fluid collection sheet (76) is able to bend against the skin (116) as the lancet (62) pierces the skin (116) to form the incision (118). In one form, the sampling end portion (106) is as long or longer than the tip (80) of the lancet (62) which allows fluid to be collected when the lancet (62) is removed from the incision (118). To put it another way, the length of the fluid collection sheet (76) is able to compensate for variations in the relative distance between the device (60) and the skin (116) that are caused by numerous sources, such as variable skin elasticity and/or variable retraction distances. In other words, the fluid collection sheet (76) increases the effective range or chance that fluid will be drawn successfully. The long fluid collection sheet (76) allows the firing mechanism to be biased to draw the lancet completely out of the incision. As illustrated in FIG. 3, the flexible nature of the fluid collection sheet (76) also does not significantly deform the skin (116) such the incision (118) in the skin

(116) remains open during collection of the fluid sample. If the sheet were rigid, however, the skin (116) would tend to deform such that the incision (118) would prematurely close, thereby cutting off the fluid supply. The fluid collection sheet (76) can also provide a visual (and/or tactile) cue that the device (60) is positioned properly to collect the fluid sample, and in one form, the sheet is transparent so that the user can visualize fluid collection better. Alluded to before, the design of the integrated device (60) also allows it to be manufactured easily and inexpensively. The fluid collection sheet along with the lancet being fixed allows the device to be made through a high-speed reel-to-reel type process.

### ***Independent Claim 1***

At the interview, an amendment to claim 1 was proposed that addressed the informality in item 8 as well as clarified that the flexible sheet was configured to bend against the skin as the lancet forms the incision. Based on the Examiners' remarks from the Interview, claim 1 has been further amended to incorporate some additional features that clearly distinguish it from the cited references. In particular, claim 1 now recites that "the lancet tip extending from the capillary channel opening, the lancet tip being immovable relative to the housing" and "the sampling end portion of the flexible sheet being at least as long as the lancet tip to draw the bodily fluid into the opening of the capillary channel when the lancet tip is retracted from the incision." As mentioned before, the flexible collection sheet facilitates successful fluid collection with minimal pain for integrated disposables that have a fixed lancet design, thereby making a fixed lancet design a commercially viable option. By being at least as long as the lancet tip, the fluid collection sheet is able to collect fluid from the incision without the need for the lancet to still be painfully located inside the incision. This allows for greater leeway in positioning the device during fluid collection.

As should be recognized, none of the references of record disclose this feature. For example, U.S. Patent No. 6,143,164 to Heller et al. ("Heller") does not disclose a flexible fluid collection sheet that is at least as long as an immovable lancet tip. Heller merely states at column 11, lines 11-16 "The sorbent material 34 may include a tab 33 which is made of the same material as the sorbent and which extends from the sensor, or from an opening in the sensor, so that a sample may be brought into contact with tab 33, sorbed by the tab, and conveyed into the sample chamber 26 by the wicking action of the sorbent material 34." Nowhere does Heller ever

specify the length of the tab 33 that extends from the sensor, and further, Heller never provides any illustration of the tab extending from the sensor so as to illustrate its relative length, especially relative to an immovable lancet. The other remaining references of record fail to remedy this missing feature. For instance, US 2003/0028087 A1 to Yuzhakov et al. (“Yuzhakov”) does not disclose a fluid collection sheet, let alone its length. For these and other reasons, claim 1 and its dependent claims are in condition for allowance.

### ***Independent Claim 32***

Independent claim 32 has also been amended to highlight some unique and inventive features. For example, none of the cited references disclose or suggest the steps of “bending the flexible sheet against the skin during said lancing”, “straightening the flexible sheet during said retracting” and “drawing the bodily fluid from the incision into the capillary channel with the flexible sheet” as is now recited in claim 32. Heller clearly does not expressly disclose these steps. Moreover, there is no inherent disclosure of such missing features. For an element to be inherently disclosed, it must “necessarily be present in the thing described in the reference.” In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Indeed, inherency “may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” 49 USPQ2d at 1951. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 1464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original). It is quite conceivable and in fact likely that the sensor of Heller does not contact the skin during lancing such that any part of the tab extending from the sensor would not bend. Consequently, it is not a necessary consequence that the tab of Heller bends during lancing; it is not inherent to the disclosure of Heller. The other references of record do not remedy this missing feature. For example, Yuzhakov does not even disclose the recited flexible sheet, let alone one that bends during lancing. For these and other reasons, claim 32 and its dependent claims are in condition for allowance.

### ***Independent Claim 47***

Independent claim 47 has further been amended to highlight some unique and inventive features. For example, none of the cited references disclose or suggest “a sheet of hydrophilic film extending from the opening of the channel, the sheet being flexible to bend as the lancet tip forms the incision; and the sheet extending past the lancet tip for drawing the bodily fluid into the channel” as is now recited in claim 47. As discussed before, Heller does not disclose the relative length of the tab 33, and the other references fail to remedy this missing feature. For these and other reasons, claim 47 and its dependent claims are in condition for allowance.

### ***Independent Claim 57***

Independent claim 57 has been added to provide additional coverage. As should be recognized from the previous discussions, none of the references of record, like Heller or Yuzhakov, disclose or even suggest “the lancet tip extending in a fixed manner from the capillary channel opening” and “the sampling end portion of the fluid collection sheet being at least as long as the lancet tip for drawing the body fluid from the incision into the capillary channel opening” as is recited in claim 57. For these and other reasons, claim 57 and its dependent claim are in condition for allowance.

### ***Independent Claim 59***

Independent claim 59 has been added to provide additional coverage. As should be recognized from the previous discussions, none of the references of record, like Heller or Yuzhakov, disclose or even suggest “bending the fluid collection sheet against the skin during said cutting the incision” as is recited in claim 59. For these and other reasons, claim 59 and its dependent claim are in condition for allowance.



### ***Conclusion***

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

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